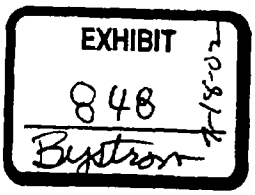
Expert Report

Dale Bystrom, R.Ph.

Duramed Pharmaceuticals Inc. vs. Wyeth-Ayerst Laboratories, Inc., Civil Action No. C-1-00-735, In the United States District Court for the Southern District of Ohio



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I. Executive Summary

Drug costs are rising faster than inflation, and becoming a large percentage of the overall healthcare spend. By 2010, it is expected that drug expenditures will be approximately 13.8% of national health expenditures, up from 6.10% in 1995 and 8.2% in 1999.[1]

The distribution of and payment for pharmaceuticals is a complex system involving patients, prescribing physicians, pharmacy providers, managed care organizations (MCOs), pharmacy benefit management companies (PBMs), pharmaceutical manufacturers and wholesale distributors.

The managed health care industry has grown to the point at which the majority of Americans now have some type of drug benefit insurance designed to deliver cost effective pharmaceutical therapy.

The managed care influence on the pharmacy industry has resulted in evolving contractual relationships between pharmaceutical manufacturers, PBMs, MCOs and pharmacy providers. These contractual relationships have influenced physician prescribing choices, and pharmaceutical product market share.

One of the health care industry's largest pharmaceutical manufacturers, Wyeth-Ayerst, dominates a category of pharmaceuticals, known as conjugated estrogens. Wyeth's conjugated estrogen product is called Premarin.

Wyeth leveraged their dominant position of Premarin, with the nation's largest health plans, MCOs and PBMs, to preempt the market entry of Cenestin, a new conjugated estrogen product manufactured by Duramed.

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[1] Heffler, Stephen, et al., "Health Spending Growth up in 1999; Faster Growth Expected in the Future" *Health Affairs*, no. 2, (March/April2001): 194.

II. Scope of Work and Qualifications

Duramed Pharmaceuticals, Inc. has retained me to prepare a report explaining retail pharmacy and pharmacy benefit management companies (PBMs) and their interface within the managed health care industry.

My report will focus on the technical and financial aspects involved in the delivery of pharmaceutical products in the retail pharmacy setting. I will report on the strategic marketing activities implemented by Wyeth-Ayerst Laboratories, Inc. that resulted in Duramed's product, Cenestin, being excluded from the formularies of most managed care organizations in the United States.

My report is based on industry articles I have reviewed together with my own thirty-five years of experience in the retail pharmacy and PBM industries. In preparing my report I have reviewed Wyeth-Ayerst and Duramed documents.

I have not ever testified as an expert in deposition or at trial.

I am a pharmacist licensed in the state of California. I have worked as a pharmacist in numerous retail practice settings. I have functioned in many different positions within a multi-state chain retail pharmacy corporation, including Third Party Administrator and Vice President of Managed Care Services. I have started up a PBM in the state of California for a major chain drug retailer. I played an active role in the implementation of a merger between two national PBMs, after which I functioned as a Co-General Manager of the merged entity. I have been a member of numerous advisory committees for the pharmaceutical industry, in the private as well as the public sector. I have also consulted for several different companies nationally within the health care industry. My background is detailed in the attached curriculum vitae (see **Attachment A**). I am being compensated at the rate of $300 per hour.

III. Pharmacy Industry Background

A. Pharmaceutical distribution system

Multiple entities are involved in the distribution of pharmaceutical products, from manufacturer to consumer. The primary participants in this distribution system are pharmaceutical manufacturers, wholesale distributors, retail pharmacies, mail order pharmacies, governmental agencies, physicians, and pharmaceutical benefit management companies (PBMs).

Manufacturers, such as Pfizer, Wyeth and others, distribute their pharmaceuticals to wholesale distributors, such as Amerisource/Bergen and McKesson, and directly to retail chain, mail order and independent pharmacies. Pharmacies acquire some or all of their pharmaceuticals through drug wholesalers and from pharmaceutical manufacturers. Pharmacies complete the distribution process providing pharmaceuticals to the end user, the patient, upon the written order of the patient's physician.

PBMs enter into pharmaceutical acquisition contracts with manufacturers and pharmacy network contracts with pharmacies to distribute pharmaceuticals to their clients' enrolled members, third party patients. PBMs act as aggregators of pharmaceutical providers and patients providing an efficient delivery system for pharmaceutical products and services.

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B. Pharmaceutical payment system

1. Payment cycle for pharmaceuticals

Much like the distribution process for pharmaceuticals, the payment cycle also involves multiple entities in the flow of financials from the patient back to the pharmaceutical manufacturer.

Pharmacy patients can be divided into two categories, "cash patients" and "third-party" patients. Cash patients pay for their prescriptions in total with their own cash out-of-pocket, whereas third-party patients have a health plan or governmental agency paying part or all of their prescription costs.

The payment cycle for pharmaceuticals begins at the pharmacy with the patient and/or patient's health plan, paying the pharmacy their usual and customary retail price, or negotiated contract price, for their prescription.

PBMs function as fiscal intermediaries between a patient's health plan and their pharmacy provider, administering payment to the pharmacy on behalf of the health plan, for pharmacy services provided to their members.

The pharmacy provider pays the wholesaler, or drug manufacturer if they acquired the drug directly from the manufacturer, an acquisition cost for the pharmaceutical products they dispense.

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In some cases the drug manufacturer pays a rebate back to the PBM for specific drugs dispensed to their members that are on the PBM's formulary. PBMs usually share a portion of the manufacturer's rebate with their health plan clients.

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2. Establishment of acquisition cost for pharmaceuticals

Pharmaceutical manufacturers establish a suggested wholesale price (SWP) for each of their products, unique by strength, dosage form and package size. The average of the SWP prices charged by the national drug wholesalers for a given pharmaceutical product is referred to as the product's "average wholesale price" or, AWP.[2]

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AWP is the industry benchmark from which most brand pharmaceutical pricing formulas among PBMs, pharmaceutical manufacturers and pharmacies are derived.

AWP is published and maintained by industry sources such as the "Red Book", published by Thompson Medical Economics, and "First DataBank" of San Bruno, California, the world's leading supplier of healthcare knowledge bases.

Drug wholesalers acquire their brand pharmaceutical products from manufacturers at a discount off of the AWP price, which is then referred to as the "wholesale acquisition cost" or WAC (e.g. AWP-17%).

Pharmacies acquire their brand pharmaceutical products from drug wholesalers at a discount off of the AWP price, usually between 17% and 21%; or directly from manufacturers at their "direct catalog price" (DCP).

PBMs enter into contracts with retail pharmacies with defined reimbursement terms for prescription services provided to their members. Those reimbursement terms reflect a discount off of the brand drugs' cost (e.g. 10% to 17%), plus a dispensing fee (e.g. $1.00 to $3.00)

PBMs also enter into contracts to obtain rebates from the manufacturers in exchange for placement on the PBM's formulary. Drug manufacturer rebates are usually defined as a percentage of the cost of the drug dispensed (e.g. 3% to 15%).

Pharmaceutical manufacturers may also pay administrative fees to PBMs for administering programs that include distribution of their brand pharmaceutical products. These administrative fees are usually defined as a percentage of the AWP price of the manufacturer's brand drugs being dispensed (e.g. 1% to 3%). PBMs usually pass on some of the manufacturer's rebate received to their client, but do not pass on the administrative fee received from the manufacturers.

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[2] American Society of Consultant Pharmacists, WWW.ascp.com/public/ga/awp/awpinfo.shtml, 6/5/00

At the point of service in a retail pharmacy when a patient receives their prescription they pay 100% of their prescription cost if they are a "cash" patient or, if they are a third party patient, they pay a portion of their prescription cost, the copayment, with the remainder of the cost billed to their health plan that subsequently pays the pharmacy.

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IV. PBMs

A. PBM Overview

In response to dramatic managed care growth and the resulting unmet need for pharmacy benefit management, specialized companies came into existence to provide prescription drug benefit management for a broad spectrum of customers. These pharmacy benefit management companies, commonly referred to as PBMs, have taken a dominant role in the management of prescription drug benefits.

PBMs originally developed from insurance claim processing and mail order prescription companies to manage their drug benefits. PBMs manage pharmacy benefits for employers, insurance companies, managed care groups, and Medicaid. There are approximately 100 PBMs in the U.S., but the top four companies account for more than 50% of the reported PBM lives.

PBMs may provide administrative services and/or clinical services to their clients. Administrative services include client service, pharmacy network administration, mail pharmacy, claims adjudication, member services, and manufacturer contracting and rebate administration. Clinical services range from formulary management to sophisticated disease management programs.

In general, self-insured employers and insurance carriers outsource both administrative and clinical services to a PBM. Managed Care Organizations (MCOs), including HMOs, and some insurers may elect to retain formulary and clinical control, including manufacturer contracting, and outsource only administrative services, such as claims processing and benefit administration, to a PBM.

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PBM services revolve around the drug benefit designed by the client. The benefit design determines the therapeutic categories of drugs that are covered -including whether cosmetic, lifestyle, and over-the-counter (OTC) drugs are reimbursed-and the extent to which generics and formulary drugs are mandated.

PBMs function as aggregators in the pharmacy industry. They aggregate large patient populations through their contracts with health plans, self-insured employers, municipalities, and other clients. These large groups of prescription purchasers provide leverage for the PBMs in their negotiations with pharmacies when contracting for their prescription reimbursement rates.

PBMs also aggregate pharmacy providers to create pharmacy networks for their clients to which their members are directed when needing prescription services. PBMs often leverage participation in their pharmacy network, or potential exclusion from their network, in their prescription reimbursement negotiations with pharmacies for discounted prescription pricing.

PBMs also rely on their large aggregated population groups for leverage when negotiating with drug manufacturers for rebates for their managed care organization

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(MCO) clients. These large population groups give the PBMs the ability to influence market share of pharmaceutical products through their formulary process and pharmacy benefit plan design features. Market share is a very important issue to pharmaceutical manufacturers. The rebates pharmaceutical manufacturers pay to PBMs are often tied to the market share of their pharmaceutical products.

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The four largest PBMs dominate the PBM industry, collectively administering pharmacy benefit services for over half of the U.S. population. In addition, some larger PBMs "rent" their formularies to smaller PBMs, passing back the rebates that are paid by manufacturers for brand drugs purchased by the smaller PBM's clients' members. This practice of renting out formularies aggregates additional population groups for the larger PBMs to use in their negotiations for rebates from the pharmaceutical manufacturers.

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B. PBM Market Consolidation

The PBM market is led by AdvancePCS, Merck-Medco Managed Care, L.L.C. (Merck-Medco), Express Scripts Inc. (Express Scripts), and Caremark Rx, Inc. (Caremark), with the remainder of the market split between smaller PBMs such as Prescription Solutions, insurer owned PBMs such as Wellpoint, and PBMs operated by retail chains such as Walgreens Health Initiatives. It is estimated that the top four PBMs control over 200 million covered lives, more than half the population of the United States. The total number of reported covered lives by PBMs (400,000,000) significantly exceeds the total population of the US, primarily because of double counting. For example, a state government with 3 million members may contract with one PBM for retail services and another PBM to provide mail service. In this case, both PBMs count the same 3 million members.

PBM Market Segments

Segment	Description	PBM	Covered Lives
Tier 1	>20 million covered lives.	AdvancePCS	85,000,000
		Merck-Medco	65,000,000
		Express Scripts	48,000,000
		Caremark Rx	20,000,000
Tier 2 and Retail	Smaller PBMs and those owned by retail chains	New Eckerd Health Services	5,000,000
		Prescription Solutions	5,000,000
		Prime Therapeutics	5,000,000
		Walgreens Health Initiatives	4,000,000
Captives	Insurer-owned PBMs	Wellpoint	30,000,000
		Aetna	5,000,000
Other	Other PBMs		128,000,000
		Total	400,000,000

The four largest PBMs each manage greater than 20 million covered lives, own mail pharmacies, and have extensive retail pharmacy networks with national coverage.

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C. PBM services / client contracts

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PBMs help to manage pharmacy benefit costs for their clients in several ways, two of the most effective of which are (1) retail pharmacy price discounting, and (2) obtaining rebates from brand pharmaceutical manufacturers.

PBMs develop national pharmacy networks that are under contract to provide prescription dispensing services at negotiated reimbursement rates, offering discounted prices to their client's members. PBMs will often negotiate price discounts with retail pharmacies reflective of the size of the population base represented by their clients' members and the number of competing pharmacies included in the PBM's pharmacy network; the larger the population of members and the more restrictive the pharmacy network, the greater the discount negotiated by the PBM for pharmacy services on behalf of their client.

PBMs offer formulary services to their clients as a cost containment tool. Formularies assist physicians in making cost-effective drug therapy choices. Formularies also attract rebates from the brand pharmaceutical manufacturers which have their products listed on the PBM's formulary.[3]

D. Drug Formularies

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Formulary management is the process of developing and maintaining a list of preferred drugs, [illegible] intent of promoting cost-effective clinical care.[4] When multiple drugs exist with similar clinical results, issues such as cost-effectiveness and maximizing manufacturer rebates determine which drugs are included on the formulary. A drug's inclusion on formulary is a prerequisite for that drug to be eligible for rebates from its manufacturer. Formularies are created and administered by PBMs or MCOs.

A formulary is a continually updated list of brand and generic drugs developed by the Pharmacy and Therapeutics (P&T) committee of the PBM or MCO. Formularies often contain relative cost indices for comparable drugs, highlight preferred brands, and include treatment protocols, usage guidelines, and other clinical information. Formularies are typically distributed to primary care physicians, but patients and pharmacists may also receive them. Electronic messages are often returned to pharmacists during claims adjudication indicating formulary status of the drug being dispensed. Formularies are typically produced yearly or every other year, with quarterly updates distributed during the interim.

PBMs use formularies to encourage the use of specific brand (and generic) drugs, which are typically the basis for rebates (and administration fees) paid by pharmaceutical manufacturers. Manufacturers pay rebates to have their brand drugs listed on formularies.

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[3] "Concepts in Managed Care Pharmacy Series: Formulary Management," The Academy of Managed Care Pharmacy, April 30, 1998. www.amcp.org. Link to Concepts in Managed Care Pharmacy.

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Clients can develop their own formulary or customize their PBM's national (i.e., standard) formulary to develop one that better meets the needs or preferences of their practitioners and patients. This is typically done by health plans that have their own Pharmacy and Therapeutics (P&T) committee.

When customizing a formulary, PBMs encourage their clients to consider the impact that deviations from the PBM's national, standard, formulary can have on their rebates.

PBMs routinely administer customized formularies on behalf of their MCO clients. Some large MCOs negotiate rebates directly with manufacturers and administer their own rebate programs.

Formulary management services allow a client to use the PBM's formulary and share in the manufacturer rebates. In general, employers and insurers have the least restrictive drug programs and will use their PBM's formulary, while MCO's have the most restrictive formularies and are more likely to develop their own formulary list of approved drugs. Drug formularies can be "open", "incentivized", or "closed".

An **Open Formulary** is a list of recommended or preferred drugs. Under this structure, most drugs are reimbursed irrespective of their formulary status. However, the client's drug benefit plan design may exclude certain drugs (i.e., OTC, cosmetic and lifestyle drugs). Some open formularies may contain patient incentives, such as differential copayments.

An **Incentivized Formulary** applies differential copayments or other financial incentives to influence patients to use, pharmacists to dispense, and physicians to write prescriptions for formulary products.

A **Closed Formulary** limits reimbursement to those drugs listed on the formulary. Non-formulary drugs may be reimbursed if, on an exceptional basis, the drugs are determined to be medically necessary by the health plan.

Physicians, pharmacists, and health plan members are encouraged by PBMs, via mailings, electronic messaging, and other means, to prescribe and dispense formulary drugs. Plan members can also be incentivized financially to use formulary drugs.

Evidence of the prevalence of different formulary types is mixed. About three-fourths of HMOs have preferred or closed formularies (45% preferred or partially closed and 27% closed) (Novartis 1999). There has been a trend away from closed formularies, toward more preferred or partially closed formularies. Health care plans that are more closed systems, such as staff model HMOs; have higher rates of closed formularies (36.4%). In contrast, a survey of employers using PBMs revealed most employers (80%) have open formularies, with only 10% having either a closed or preferred (incentivized) formulary (Wyeth-Ayerst 1999). An explanation postulated in the report for the low use of closed or preferred formularies was that employers value rebates less than unrestricted access and member satisfaction; however, among employers, closed or incentivized formularies are increasing in popularity.

Some PBMs maintain relatively open formularies, but rank drugs of a given therapeutic class according to their cost, usually indicated by dollar signs – one $ for the least expensive, up to five or even six $ for the most expensive. The cost ranking does not necessarily reflect the retail cost of the drug, but its cost reflective of discounts and rebates.

E. Copayment structure description

Cost sharing requirements in prescription drug programs require consumers to pay a portion of the cost of each prescription they obtain. This is referred to as the patient's copayment. As a cost control effort of PBMs, copayments are targeted toward consumers in an attempt to shift some responsibility to them for the cost of their prescription utilization, raise their sensitivity to the cost of that utilization, or to encourage consumers to purchase formulary drugs that earn the PBM lucrative rebates. Effectively, copayment requirements are a component of the benefit structure for prescription drug coverage and thus can vary across health plans managed by a given PBM.

Copayments are also used to provide incentives to encourage the use of generic drugs and formulary brand drugs, which often are the drugs for which the PBM receives rebates from drug manufacturers.

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1. Two Tier Copayment Plans:

Traditionally, prescription drug benefits require that the insured pay a minimal copayment, typically $5 for generic drugs and $10 or $15 for brand name drugs. The costs of non-formulary drugs, unless approved by an established exception process, are the responsibility of the patient.[4]

2. Three Tier Copayment Plans:

Increased demand for access to drug products by health plan members and rising pharmacy benefit plan costs for the health plan payors, have resulted in rapid adoption of a three tier copayment plan design.

Three tier copayment plan designs allow non-formulary drugs to be included within a member's drug benefit, which would not have been included in the two tier copayment plan design. The health plan member is charged a tier three copayment amount when a non-formulary brand drug is dispensed within their drug benefit.

The third tier copayment is their plan's highest copayment amount, often sizably more than the formulary brand drug copayment amount, since PBMs want to discourage use of drugs that cut into the market share of their formulary drugs.

Although a three tier copayment plan design allows for non-formulary drugs to be covered by a member's health plan, the member must pay the plan's highest copayment amount to acquire a non-formulary prescription.

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[4] "Managed Care Pharmacy Practice", Robert P. Navarro, Aspen Publishers, Inc. 1999. Page 163.

F. PBM adjudication interface with pharmacy providers

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One of the key services PBMs provide is the online adjudication of drug claims from pharmacies commonly referred to as claims processing. This process examines the member's eligibility and drug coverage to determine the pharmacy's reimbursement and member's copayment. In addition, edits are applied to ensure the clinical appropriateness of the drug dispensed and to increase formulary compliance.

The claims adjudication process begins at the point of service at the pharmacy. Upon receipt of the prescription, the pharmacist enters it into the pharmacy computer along with information from the member's drug card. This information is then electronically transmitted, adjudicated, to the PBM's claims processing system.

Once the PBM's claim processing system receives the claim, it is adjudicated and the pharmacist receives a response confirming the member's eligibility and drug coverage, and stipulating the amount the pharmacy is to be reimbursed together with the member's copayment to be collected.

During claims processing, the information submitted by the pharmacy is checked against the health plan's eligibility file to validate the member's name, benefit plan, and birth date. Upon confirming eligibility, the prescription is checked against the benefit design to confirm drug coverage and the corresponding copayment to be paid by the member. The claims processing system also determines the type of network pharmacy submitting the claim (either mail or retail), and calculates the appropriate reimbursement of ingredient costs and dispensing fee for the pharmacy.

The entire adjudication process is usually completed in a matter of several seconds. The PBM claims adjudication process is an on-line real-time transaction, much like a credit card transaction.

G. PBM rebates from pharmaceutical manufacturers

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PBM contracting with pharmaceutical manufacturers most often involves negotiations between the two parties to determine positioning of the manufacturer's drug products on the PBM's formulary. Brand pharmaceutical manufacturers enter into rebate contracts with PBMs to maintain, protect or grow market share of their drug products and/or receive information and services from the PBMs. Generic drug manufacturers do not enter into these types of contracts because the PBM does not influence which generic brands are carried at the retail pharmacy.

Formulary positioning and the number of formulary drugs within a drug's product category are key factors which impact the drug's sales volume and market share within its therapeutic class.

In creating a drug formulary the issue of rebates becomes paramount to the PBM when determining formulary positioning between drugs in the same therapeutic class.

1. **Rebates represent a significant component of PBM income:**

As the PBM industry continues to consolidate the price competition for PBM services is becoming more aggressive. In order for PBMs to attract new clients there must be an incentive for such clients to transition from their existing PBM. These incentives exist as service enhancements and/or lower pricing from the PBMs for their services.

In the past PBMs have obtained a substantial portion of their profits from claims administration fees charged to their clients for processing the prescriptions of their members. In addition to the claims administration fees PBMs have derived profits from drug manufacturer rebates and administration service fees, clinical service program fees, and differentials in pricing between the amount charged to their clients and the amount paid to their pharmacy providers, for member prescriptions processed.

As the PBM industry competes aggressively for new clients, the PBM profits derived from their administration fees has diminished and their manufacturer rebates with their associated administration fees have become a more significant component of the PBM's total profitability. For some PBMs brand drug manufacturer rebates and associated fees account for over 50% of their total gross margin dollars. ***This makes drug manufacturer rebates and their associated fees extremely important to the profitability of most PBMs.***

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2. **Rebate amount and allocation to the PBM's clients:**

Rebates and administrative fees are commonly calculated and paid as a percent of the drugs' cost, ranging up to 15%. Rebates greater than 15% are rare, since they might cause manufacturers to exceed their Medicaid Best Price rebates.

The Medicaid rebate program, established by the Omnibus Budget Reconciliation Act of 1990, was established to help contain government spending on outpatient prescription drugs. Under the basic rebate formula, pharmaceutical manufacturers pay a rebate equal to at least 15.1 percent of the average price they earn on sales to retail pharmacies for brand-name drugs purchased by Medicaid beneficiaries. The basic rebate is often higher than that 15.1 percent minimum because of a "best-price" provision that gives Medicaid access to the lowest price paid by any private purchaser in the United States.

The best-price provision increases the Medicaid rebate when a manufacturer gives a discount that exceeds the minimum rebate of 15.1 percent. In such cases, the Medicaid rebate is equal to the largest reported discount given to any private sector purchaser. Since Medicaid constitutes about 12 percent of the outpatient prescription drug market, pharmaceutical manufacturers are less willing to give large private purchasers steep discounts because they are required to give Medicaid access to the same low price.[5]

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[5] "Pricing Mechanisms Used By The Federal Government To Contain Prescription Drug Costs", by Anna Cook, Ph.D., Mathematica Policy Research, Inc. *August 8-9, 2000 Leavey Conference Center, Georgetown University, Washington, DC*

The allocation of rebates to a PBM's client is dependent on the client's contract with the PBM. Some large sophisticated clients, such as HMOs, receive all or a fixed percentage of the rebates collected by the PBM. Other clients may receive a guaranteed rebate per prescription claim that the PBM is obligated to provide regardless of the rebate amount actually paid by the manufacturer to the PBM. Some clients may not share in the PBM's rebate at all. Usually the larger the client, the greater the rebate sharing that occurs.

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3. Factors influencing rebate levels

There are several factors that may influence the level of rebate provided to the PBMs by pharmaceutical manufacturers for listing their drug(s) on formulary:

1. The number of drug product classes of the pharmaceutical manufacturer's products that are included in the PBM's formulary.

3. The number of individual drug products that are included within each drug product class for the contracting pharmaceutical manufacturer.

4. The degree of control over drug product selection which is afforded by the PBM's drug plan design:

   - **Low control:** The formulary is considered "open" with no prescribing restrictions within the coverage of the member's drug benefit; without benefit designs or financial incentives tied to formulary drug selection.
   - **Medium control:** There are plan design and/or financial incentives tied to formulary drug selection.
   - **High control:** The formulary may be considered "closed" in which case only those products listed on the formulary are included within the member's drug benefit; or, the formulary may indicate certain drugs as "preferred" with substantial plan design and/or financial incentives tied to preferred drug product selection, or financial disincentives associated with the selection of a non-preferred product.

4. Rebates are paid for formulary position, which impacts the market share of the pharmaceutical manufacturer's drug product.

In almost all cases a PBM's P&T committee approval is necessary for a changes to occur on their formulary. P&T committees rarely drive these formulary change decisions; instead they bless decisions made by the PBM's decision makers.

The primary concern of the pharmaceutical manufacturers is that their products are included on the PBM's formulary. They also don't want any negative positioning or financial disincentives for their drugs compared to their competitor's products.

The amounts of the rebates paid vary depending on the contracting abilities of the PBM, the number of covered lives, the pharmacy benefit, and the group's utilization patterns.[6]

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[6] "Managed Care Pharmacy Practice", Robert P. Navarro, Aspen Publishers, Inc. 1999, page 71

V. Retail Pharmacy Industry

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A. Pharmaceutical acquisition

Retail pharmacies obtain their pharmaceutical drug products almost entirely from two sources, drug manufacturers (including repackagers) and drug wholesale distributors.

In a report released on August 31, 2001, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) sampled pharmacy acquisition costs for brand name products nationally. The report indicated that retail pharmacies pay an acquisition price to the manufacturer and/or wholesaler that, in aggregate for all brand drugs, equates to AWP less 21.48%.

B. Pharmaceutical reimbursement

Pharmacies purchase pharmaceutical products from wholesalers and drug manufacturers and then sell their prescriptions to patients, most of which have a portion of their prescription costs paid by their health plan, administered through a PBM.

Pharmacies are reimbursed by the PBMs (as a pass through from their clients) for the ingredient cost of the drug dispensed plus a dispensing fee, less the member's copayment. Ingredient cost is based on the lowest of three calculations, depending on the drug dispensed: a discounted AWP, maximum allowable cost (MAC), or usual and customary (U&C). Reimbursement rates vary depending on the client and pharmacy network.

Ingredient cost for branded drugs, with no generic alternative, is typically reimbursed at AWP minus a discount percent (usually between 10% and 17%). Dispensing fees paid for branded drugs are typically $1.00 to $3.00 per prescription.

C. Claims adjudication and formulary compliance processes

There are today approximately 55,000 retail pharmacies in the United States that process between 70% and 90% of their prescriptions on-line through a PBM. There are several key factors which enable retail pharmacies to process prescriptions to a PBM in a real-time environment

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1. **Electronic transmission standards and data set definitions:**

The pharmacy industry utilizes a well-defined set of data transmission standards and data field definitions, developed and maintained by an industry-wide standards development organization, The National Council of Prescription Drug Programs (NCPDP).[7]

2. **NDC Number:**

The National Drug Code, or NDC, number uniquely identifies prescription drugs. The NDC number is used to accurately and uniquely identify drugs in the prescription-processing environment. The NDC number is the identifier used by pharmacies when submitting prescription information to a PBM for processing and payment. An NDC number is much like a UPC (bar code) number. It is a 10-digit number assigned by the FDA which uniquely describes a product and its packaging.

3. **Electronic Pharmacy Computer Systems:**

Pharmacies process prescriptions electronically through their pharmacy computer system. As previously described, when a patient submits a prescription to a retail pharmacy to be filled and dispensed, the prescription is entered into the pharmacy's computer system for processing and data warehousing. If the patient has a drug benefit that provides payment coverage for their patient's prescription, the pharmacy adjudicates the prescription information on-line, real-time to the appropriate PBM for processing and payment. The PBM verifies the patient's eligibility and drug coverage, performs numerous checks and edits on the submitted prescription information and returns electronic messages to the submitting pharmacy.

The information received from the PBM by the pharmacy will indicate several things to the pharmacist, such as:

- If the patient is eligible for prescription coverage
- If the submitted prescription is covered by the patient's drug benefit plan
- The patient's copayment amount
- Drug utilization safety messages

4. **NDC Blocks:**

NDC blocks are system edits, administered by PBMs, which are put in place to indicate that a uniquely identified drug is being blocked from coverage within a patient's drug benefit plan. NDC Blocks are sometimes applied to a specific drug within a therapeutic class indicating that drug is not included in the formulary of a patient's health plan.

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[7] NCPDP (National Council of Prescription Drug Programs) is a non-profit, standards development organization comprised of individuals and organization representatives from all segments of the third-party prescription drug program industry.

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When a pharmacy submits a drug, which has an NDC block in the PBM's system, it will receive back a "reject code" from the PBM administering the patient's pharmacy benefit. This reject code is an indication to the pharmacy that the submitted drug is not covered by the patient's health plan.

An NDC block is one of the most effective tools the PBM uses to prevent a non-formulary drug from being dispensed to a patient with a drug benefit plan.

5. **Soft Edits:**

Soft edits are advisory messages, returned to the submitting pharmacy from the PBM during the prescription adjudication process. The purpose of a soft edit message is to alert and educate the pharmacist about the prescription being processed.

Often times a soft edit message will alert the pharmacist that there is a drug which is "preferred" by the health plan as an alternative to the drug that was initially submitted by the pharmacist.

The soft edit does not stop the submitted drug from being processed and paid, unlike an NDC block, but rather it suggests to the pharmacist to consider contacting the prescribing physician and recommend an alternative drug to the one originally prescribed. (There may be financial incentives for the pharmacist to contact the physician.)

Soft edits are an effective tool that PBMs use to increase formulary compliance and preferred drug utilization in drug benefit plans that have an open formulary structure.

6. **Prior Authorization:**

Some drugs are indicated on the PBM's formulary as requiring the prescribing physician to obtain prior authorization from the member's health plan before the drug is eligible for payment by within member's drug benefit.

Prior authorizing a drug can be a significant barrier to its being prescribed by the physician and subsequently dispensed by the pharmacy provider. Prior authorizations are a discouragement for the physician to prescribe drugs that are not on formulary. Prior authorizations represent one more "hoop the physician must jump through" to get a health plan to approve payment for a non-preferred drug.

Prior authorization is usually required for the most expensive drugs, especially if there is a cheaper alternative available. Prior authorization is also frequently required even in the case of one-of-a-kind drugs for which there are no alternatives available. In these cases, prior authorization is used to make sure that the drug is not being prescribed for an unapproved use.

The process of obtaining a prior authorization for the physician can range from a relative simple process to a very complex process which may involve step therapy protocols, depending upon the cost of the medication being prior authorized relative to alternative formulary medications within the same therapeutic class of drugs.